

FACDQ Recommendations on Uses of Detection and Quantitation in Clean Water Act Programs

This Draft Revised Uses document incorporates changes made by the Policy Work Group on August 20, as well as Policy Work Group authorized assignment changes. These changes are shown in tracked changes, footnotes, and in comments.

1. Lab-Determined Detection Limits and Quantitation Limits

Recommendation: The FACDQ recommends that EPA promulgate¹ the DQFAC Single Laboratory Procedure² recommended by the FACDQ for individual laboratories to determine their detection and quantitation limits. The DQFAC Single Laboratory Procedure shall³ be used instead of the current MDL procedure in 40 CFR Part 136, Appendix B, for calculating all future Laboratory Detection and Quantitation Limits. The DQFAC Single Laboratory Procedure has the following two capabilities:

- Demonstrates the lab's performance at a specified level.
- Determines the lowest possible value achievable by the lab while meeting the measurement quality objectives (MQOs).

Comment [CG1]: shall be used "in all CWA programs"...

Comment [CG2]: Will Appendix B be put into Part 141 for Drinking Water? Labs may oppose implications of two procedures to use.

2. Matrix Effects

Recommendation: The FACDQ recommends that EPA consider how matrix effects impact detection and quantitation. The FACDQ requests that the Policy Work Group bring back a conceptual recommendation including details to be considered.

Comment [CG3]: This section will include more substantive issues pending discussion by the Matrix Effects Work Group. For example:

1. How to demonstrate a matrix effect.
2. The level of matrix effect validation during method development to be performed
3. A cost effect procedure for determining specific matrix effect identification.
4. How impacts occur and how to deal with them.
5. How are DL and QL determined when matrix effects occur

3. Verification of Laboratory Proficiency of Detection and Quantitation Limits

Recommendation: The FACDQ recommends developing a process for verification of detection and quantitation limits by laboratories which will strive for feasibility, practicality, representativeness, and cost-effectiveness. This recommendation includes the following guidance:

- The process should include separate initial and on-going verification of Laboratory Detection and Quantitation Limits.
- The process should verify that the method meets the chosen MQOs.
- The Laboratory Quantitation Limit must be equal to or lower than the National Quantitation Limit, if a National Quantitation Limit exists.

Comment [CG4]: The Verification Work Group will have material for this section shortly. They are deciding between general recommendations to EPA and specific recommendations.

¹ The FACDQ recognizes that EPA cannot commit to promulgate the recommendations of the FACDQ without the benefit of public notice and comment. Wherever "promulgate" appears in the FACDQ recommendations, the FACDQ expects that EPA will propose a rule consistent with the FACDQ recommendations and then finalize a rule that fully considers those public comments.

² This procedure was created via modifications to the ACIL.

³ The Policy Work Group proposes that a small subgroup of the Policy Work Group examine each "shall," "should," and "must" to determine if they are being appropriately used.

See Attachment A on pg. 8 for a minority opinion in favor of retaining the DL_{nat} in the Uses recommendations.

4. Promulgation of National Quantitation Limits Recommendation

See Attachment B on pg. 9 for background discussion on the following two alternatives:

Alternative 1

Initial Statement of Purpose

It is the intent of the FACDQ to recommend that EPA adopt National Quantitation Limits for method and analyte combinations, particularly where compliance with the CWA cannot be determined using currently approved analytical methods (e.g. if WQBELs are less than the analytical capability of the methods). National Quantitation Limits should be set at the lowest concentration possible using approved analytical methods. A National Quantitation Limit shall be published in each analytical method used to analyze an analyte that needs a National Quantitation Limit. National Quantitation Limits can be different for each method approved for a given analyte. National Quantitation Limits are costly to develop and are not needed for regulatory determination for most analytes currently regulated under the Clean Water Act.

New Method Promulgation

Recommendation A (Placeholder): The FACDQ recommends that EPA promulgate a [multi-laboratory or inter-laboratory] procedure recommended by the FACDQ for determining National Quantitation Limits.

Recommendation B: The FACDQ recommends that when the EPA promulgates future analytical methods in 40 CFR Part 136, National Quantitation Limits shall be created and included with the methods. A National Quantitation Limit shall be created for each analyte determined by a method using the procedure(s) in Recommendation A.

Currently, this recommendation would require method developers applying for ATP approval, and standard-setting organizations, to submit to EPA multi-laboratory quantitation limits consistent with the FACDQ's multi-laboratory recommendations. These multi-laboratory limits would serve as National Quantitation Limits should the applicant's method later be promulgated in 40 CFR Part 136. For some standard-setting organizations, this may be a significant departure from what they do now. Moreover, some FACDQ members are concerned that this requirement may stifle the development of new methods. Many of the methods recently promulgated by EPA in Part 136 are the product of these outside organizations, reflecting advances in technologies that result in methods with greater sensitivity. Therefore, the FACDQ requests that EPA discuss and request public comment on this issue in the EPA Notice of Proposed Rulemaking that incorporates the recommendations of the FACDQ. Should significant concerns surface during public comment, EPA should make appropriate changes in the final rulemaking to ensure that the development of new methods is not adversely affected.

Comment [CG5]: Added by Mary Smith as an assignment from the August 20, PWG meeting.

~~The method developer for a method may petition EPA for an exemption to the requirement to create (a) National Quantitation Limit(s). Such exemption request shall include reasons for why the exemption is appropriate.~~

~~EPA may grant exemptions to the National Quantitation Limit requirement for reasons including, but not limited to, any of the following:~~

- ~~○ The new method can easily quantify, based on preliminary information, the analyte(s) of interest at environmentally significant levels (both current and projected future levels).~~
- ~~○ The new method is obviously less sensitive, based on preliminary information, than an already approved method.~~
- ~~○ Inadequate laboratory capabilities or other economic considerations prevent the Recommendation A procedure from being fully implemented and EPA and the method developer commit to updating the method to incorporate a National Quantitation Limit once feasible.~~

Future Updates of Promulgated Analytical Methods

Recommendation: The FACDQ recommends that EPA periodically review current capabilities of promulgated analytical methods and undertake updates based on priorities. Method updates shall include creation and incorporation of first-time or updated National Quantitation Limits. A National Quantitation Limit shall be created for each analyte determined by a method using the same procedure(s) as for new method promulgation.

In determining update priorities, EPA should consider:

- Methods where there have been significant improvements in detection or quantitation limits
- Methods that do not contain National Quantitation Limits
- Cases where quantitation limits are critical to the permit program (e.g., those required for very low WQBELs)
- Analytes for which current methods provide poor performance or otherwise do not meet program needs
- Cost and resource considerations
- Information submitted by states and/or other qualified third parties.

EPA will work with method developers to update priority methods. Exemptions to the requirement to specify National Quantitation Limits shall be the same as those for new methods. EPA shall publish a Federal Register Notice announcing the methods it proposes to update to incorporate National Quantitation Limits. Provisions later in this document are for the purpose of providing EPA with robust data sets for updating and or creating National Quantitation Limits.

Comment [CG6]: Should this be deleted?

Alternative 2

Initial Statement of Purpose

It is the intent of the FACDQ to recommend that EPA adopt National Quantitation Limits for analytes listed in 40 CFR 136 based on a list of priorities. National Quantitation Limits should be set at the lowest concentration possible using approved analytical

methods when compliance with the CWA cannot be determined. However, for analytes when compliance with the CWA can be comfortably determined, EPA may set a QL- something else at a concentration that allows the maximum number of laboratories and approved methods to be used. National Quantitation Limits and QL something else shall be published in a table in 40 CFR 136 by analyte. Labs may use any approved method for an analyte so long as the Laboratory Quantitation Limit is equal to or lower than the National Quantitation Limit or QL something else for the analyte. This will provide a level playing field for all laboratories and permittees and allows maximum analytical flexibility.

Creation and Update of National Quantitation Limits

Recommendation A (Placeholder): The FACDQ recommends that EPA promulgate a [multi-laboratory or inter-laboratory] procedure recommended by the FACDQ for determining National Quantitation Limits.

Recommendation B: The FACDQ recommends that EPA periodically review capabilities of analytical methods for the purpose of establishing and updating National Quantitation Limits. Quantitation limits shall be evaluated by analyte and method using the procedure(s) in Recommendation A. For a given analyte, the method that EPA judges has the lowest quantitation limit shall be used as the basis for setting the National Quantitation Limit.

EPA shall prioritize its efforts to create National Quantitation Limits using these or other factors:

- Cases where method sensitivity issues are critical to Clean Water Act programs (e.g., analytes with very low WQBELs)
- Analytes for which available methods have seen significant improvements in detection or quantitation limits
- Analytes for which there are no current National Quantitation Limits
- Cost and resource considerations
- Information submitted by states and/or other qualified third parties

EPA will work with method developers and others to establish and update National Quantitation Limits. EPA shall publish a Federal Register Notice announcing the analytes for which it proposes to create or update National Quantitation Limits. Provisions later in this document are for the purpose of providing EPA with robust data sets for creating or updating National Quantitation Limits.

5. Setting Permit Conditions, Reporting and Using Data, and Determining Compliance When the Water Quality Based Effluent Limit (WQBEL) is Less Than Detection and Quantitation Capabilities of Existing Methods⁴

⁴ The language previously here, relating to WQBELs at concentrations less than quantitation limits, was recommended as more appropriate elsewhere within the Final Report text and has been removed from the Uses document.

Recommendation: The FACDQ recommends that the following recommendations be incorporated into 40 CFR Part 122, as appropriate.

A. Recommendations for NPDES Permit and Compliance Uses When a National Quantitation Limit Exists

If the permitting authority requires use of a method more sensitive than the method for which a QL_{nat} exists, go to section B.

1) Permit Requirements Related to Detection and Quantitation

Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 136:

- a. The default quantitation limit to be included in the permit (Permit Quantitation Limit) is the lowest Part 136 promulgated National Quantitation Limit unless the regulator determines that the Permit Quantitation Limit should be adjusted to account for sensitivity, selectivity, and/or matrix effects;
- b. The permit shall contain a condition that the quantitation limit determined by the permittee's laboratory (Laboratory Quantitation Limit) shall be at or below the Permit Quantitation Limit. The permittee's laboratory may use any Part 136 method for which they can demonstrate a Laboratory Quantitation Limit at or below the Permit Quantitation Limit. If matrix effects have been given special attention in the permit then they would also have to be considered in compliance and enforcement.
- c. The permit shall require the permittee to report the detection limit (Laboratory Detection Limit) and the Laboratory Quantitation Limit and maintain such information for a period of at least five years;
- d. The permit shall require the permittee to maintain individual numeric results for a period of at least five years. The regulator may require the individual numeric result for any value that is greater than or equal to the Laboratory Detection Limit and less than the Permit Quantitation Limit be reported in a supplemental report.
- e. The permit shall require that the Laboratory Detection Limit and the Laboratory Quantitation Limit be determined using the steps of the 40 CFR Part 136 procedure to establish the lowest possible value by the laboratory;
- f. The Permit Quantitation Limit shall be applicable for the term of the permit unless the regulator reopens and modifies the permit; and
- g. That EPA require the Laboratory Detection Limit, the Laboratory Quantitation Limit, and the Permit Quantitation Limit be reported by the regulator to the Integrated Compliance Information System (ICIS) for purposes of updating 40 CFR Part 136 National Quantitation Limits.

Comment [CG7]: This has not been fully vetted by the PWG.

2) Establishing Compliance Thresholds and Determining Compliance

Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 136:

- a) Regulators will set average and daily maximum permit limits at the WQBEL.

- b) Permittees must report to the regulator all information in the following manner on the Discharge Monitoring Report (DMR):
 - i) To report daily maximum sample results:
 - a. For values not detected at the Laboratory Detection Limit, report “not detected”.
 - b. For values detected at the Laboratory Detection Limit but less than the Permit Quantitation Limit, report “detected less than the Permit Quantitation Limit”.
 - c. For values greater than or equal to the Permit Quantitation Limit, report the actual numeric values.
 - ii) To report average sample results:
 - a. When all values used to calculate an average are not detected at the Laboratory Detection Limit, report “not detected”.
 - b. When all values used to calculate an average are “detected less than Permit Quantitation Limit,” report “detected less than the Permit Quantitation Limit.”
 - c. When values used to calculate an average are a combination of “not detected” and “detected less than the Permit Quantitation Limit”, report “detected less than the Permit Quantitation Limit”.
 - d. When any value used to calculate an average is greater than or equal to the Permit Quantitation Limit, report the calculated numeric average after assigning zero to any individual value reported either as “not detected” or “detected less than the Permit Quantitation Limit.”
 - c) To determine NPDES permit compliance with results reported on the DMR, regulators will:
 - i) Determine that any daily maximum or monthly average results reported as either “not detected” or “detected less than the Permit Quantitation Limit” are in compliance with the effluent limitation.
 - ii) Compare any numeric results directly to the WQBEL

3) **Additional Permit Requirements**

Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 136: Permits shall include language that triggers additional steps when a “significant number” (to be determined in permitting process) of values detected at the Laboratory Detection Limit but less than the Permit Quantitation Limit are reported. These steps may include additional or accelerated monitoring, analytical studies such as matrix studies, pollutant minimization programs, or other permit conditions outside of the determination of compliance with effluent limitations. Reports under such provisions will be done outside of the DMR process, except that any additional effluent testing performed using approved analytical methods as part of the special studies must be reported on the DMR.

B. Recommendations for NPDES Permits and Compliance Uses When No National Quantitation Limit Exists, or if the Permitting Authority Requires Use of a Method More Sensitive than the Method for Which a National Quantitation Limit exists:

Recommendations:

- 1) In the absence of a National Quantitation Limit, the permitting authority is free to establish its method for determining compliance for analytes that have limits/water quality standards at a level lower than that which can be detected and/or quantified.
- 2) For a list of analytes as defined by EPA, the permit shall require that the Laboratory Detection Limit and the Laboratory Quantitation Limit be determined using the steps of the 40 CFR Part 136 procedure to establish the lowest possible value by the laboratory;
- 3) That EPA require the Laboratory Detection Limit and the Laboratory Quantitation Limit and the Permit Quantitation Limit be reported by the regulator to the Integrated Compliance Information System (ICIS) for purposes of updating 40 CFR Part 136 National Quantitation Limits.

6. Great Lakes Initiative

Recommendation: The FACDQ recommends that the FACDQ recommendations should not supersede the current Great Lakes Initiative provisions. The FACDQ believes that there is not a significant conflict between the FACDQ recommendations and the Great Lakes Initiative.

7. Other Uses to Consider

Recommendation: The FACDQ tabled the discussion on recommendations regarding the use of detection and quantitation for other uses including, but not limited to, the following:

- ambient monitoring 305(b)
- pretreatment
- non-regulatory operational monitoring
- stormwater monitoring
- other studies, such as fish tissues or biosolids characterization
- reasonable potential analysis
- effluent guidelines development
- limit derivation
- development of water quality criteria

8. Alternative Test Procedures

Recommendation: The FACDQ tabled the option of developing specific recommendations to EPA on updating the Alternative Test Procedures (ATP) Program. The FACDQ, however, does recommend that the ATP Program be updated to be consistent with recommendations from this document.

Attachment A

Written by: **David Kimbrough**

Minority Report on DL-nat

At the December 2006 FACDQ meeting, the Committee voted unanimously on a document that recommended that EPA should establish National Quantitation Limits (QL-nats) and National Detection Limits (DL-nats) and publish them in a table in 40 CFR 136. The language about a table of QL-nats and DL-nats was withdrawn by the FACDQ at the June 2007 meeting. The PWG has also recommended that the entire concept of DL-nat be removed from all documents. At the July 25 meeting of the FACDQ the Committee was unable to reach consensus on withdrawing the DL-nat. There were two “not opposed” votes and one “opposed”. This paper attempts to explain the minority position on this vote.

- 1) The first reason for keeping the concept of a DL-nat is to ensure that there is adequate “distance” between the DL-lab and the QL-nat. The FACDQ recommendations are for a two tiered approach with both a QL and DL. Results below the DL are reported as ND, results between the QL and DL are reported as DNQ, and results above the QL are reported as numeric values. ND and DNQ results are treated for averaging purposes as zero (i.e. not out of compliance) but there are important regulatory implications to DNQ results. Permittees reporting DNQs may be required to engage additional management practices such as increased or additional monitoring, special studies, or Pollutant Minimization Programs (PMPs). For this strategy to work, the values of QL and DL have be sufficiently different to allow for DNQs to be detected. In particular, it is by far most important when the WQBEL (or other regulatory limits) have lower concentrations than the capability of currently approved 40 CFR 136 analytical methodology can achieve. The FACDQ is proposing that at least in these cases, if not all, that a fixed QL-nat needs to be established. In having a DL-nat can be used as a ceiling on the DL-lab, ensuring that the DL-lab is not too high as to preclude the determination of DNQ.
- 2) The second reason for keeping the DL-nat is ensure equal protection to all receiving bodies with a given WQBEL and equity for all permittees discharging to receiving bodies with a given WQBEL. As noted above, the FACDQ recommended permitting strategy includes required management practices when DNQs are reported. As the pilot study showed, laboratories can produce DL-labs with concentrations that differ over orders of magnitude. If only the DL-lab is used, two permittees could be discharging water to a receiving body with the same concentration of an analyte, one would have to do a PMP and the other would not simply because of differences in the laboratory capability. In fact, with the range of differences in DLs seen in the pilot study, it would be possible for the dischargers with a higher concentration to have no PMP than a discharger with a lower concentration. This does not provide equal to protection to all waters nor equity to permittees.

Attachment B

Written by: **Tom Mugan**

Discussion of Alternatives for EPA Promulgation of QLnat

Work of the small group to investigate possibilities for QLnat promulgation (the small group was Tom Mugan, Richard Burrows, David Kimbrough and Michael Murray)

Alternative 1 in the August 15, 2007 Uses Document is basically the concept that was originally proposed perhaps a year or more ago.

The Alternative 1 proposal has two components.

- The first component would require a method developer of a new method to do the QL_{nat} procedure as part of method development and validation as part of the EPA promulgation procedure. The idea was that the QL_{nat} would be included with the method.
- The second component is a process that recommends that EPA update previously promulgated methods to include QL_{nats} (or update them) along with any other method improvements warranted. A number of Committee members have expressed the desire for EPA to undertake method updates on a much more regular basis. Again, the QL_{nat} would be included with the method.

The only significant recent change is that we added a process whereby a method developer could petition EPA for an exemption to the requirement to do the QL_{nat} procedure (multi-lab or inter-lab procedure). This was added in response to a concern that the requirement for new methods would stifle the development of new methods because method developers would have difficulty generating the QL_{nat}. *(This added language was later shown in strike-out because Mary suggested that a new administratively complex exemption process would be problematic. As a possible solution, she suggested that, when EPA proposes the requirement for QL_{nats} for new methods, it could specifically request comment on whether this requirement, if promulgated in the final rule, would stifle new method development.)*

The other change is the insertion of what is called an Initial Statement of Purpose as an additional explanation on the intent of the recommendation.

Alternative 2 was submitted in response to a continued concern that method developers would have difficulty finding enough labs to generate the necessary data to run the QL_{nat} procedure due to the difficulty of finding enough labs to generate the necessary data to run the QL_{nat} procedure. Therefore, Alternative 2 only has the update component.

With only an update component, it seemed reasonable that, to save on costs, EPA would only undertake update for problem analytes and, for a given analyte, would invest effort only for the method it thought was the most sensitive. Therefore, Alternative 2 was drafted as an update by analyte, rather than an update by analyte and method.

Once that draft was on paper, David K. thought that we needed to have a QL_{nat} for every analyte (in a table). Alternative 2 was then modified to say that, for analytes where current methods exist that are capable of measuring to environmentally significant levels (non-bad boys), EPA may promulgate QL_{something else} (for lack of a better name) that were reflective of a value that represents the lowest environmentally significant level. The different name is to distinguish it from a QL_{nat} that is considered to be the lowest reasonably achievable level a lab can reach.

Again, the Statement of Purpose was added.

Analysis of Alternative 1 and Alternative 2

The original vision of Alternative 1 came from the Hybrid Document many months ago. The idea was to set the ship in the right direction by developing QL_{nats} as we go forward. Thus, anytime a method is promulgated, either a new method or when an existing method is updated, a QL_{nat} would be generated and available for states to use for regulatory purposes.

The idea that implementation of the FACDQ's undertaking would need to be phased in carefully has guided a number of proposals in the uses document. If we develop a new method and do not generate a QL_{nat}, we may lose the opportunity that comes with the new method promulgation. History shows that bureaucratic momentum has a way of preventing EPA or states from re-opening a provision in law. Thus, while we may have good intentions of updating a method within a reasonably short time frame, the likelihood is not good.

A number of caucus groups have advocated for EPA being more responsive in promulgating and updating methods. Both alternatives recommend that EPA update methods to insert and revisit QL_{nats}. Would the hue and cry (and the pressure on EPA to update a method) be greater if an initially set QL_{nat} was demonstrated to be either too high or low or if there were no QL_{nat} at all?

We are trying to assess the validity of the concern of stifling method development. During a recent Policy WG discussion, Cary indicated that those applying for ATPs are already doing the QL_{nat} procedure. Cary is going to ask representatives of ASTM and Standard Methods if it might pose a problem with future methods they develop.

One attractive aspect of providing QL_{nats} by analyte, as is the case in Alternative 2, is that this appears to avoid the perceived difficulty (discussed as part of the discussion on the Uses Document) of permit conditions in a situation where the only method that has a QL_{nat} is regarded to be not the most sensitive one. This difficulty has been identified on several occasions and fixes have been made to the Uses Document.

Having a single QL_{nat} for an analyte may cause difficulties when there may be one or more methods available and there are matrix effect issues for what would otherwise be the most sensitive method. Without each method having a QL_{nat}, there would be little basis for deciding which other method is most appropriate. If we go with this alternative, we may need to provide for solutions to those problems.

Author's Privilege (Commentary by Tom Mugan)

Obviously, the Committee should try to come up with the best recommendations we can make but we should also recognize that the FACDQ is nearing the end of its charter. When the issue of stifling method development was brought forward, some discussion reverted back to topics that we had discussed and apparently reached consensus on months before (e.g. table versus no table of QL_{nats}). If we are to have any hopes of completing the most important aspects of our charge, we should refrain from revisiting past decisions.

The Initial Statement of Purpose adds length. This might be needed in a regulation where the meaning of words could be used for legal argument. In this case, if we need additional words to clearly state our intent, I think they should appear in the recommendation itself.